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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,659	08/31/2001	Gregory R. Mundy	A061CIP1	2421
1473	7590	10/03/2003		
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			EXAMINER HADDAD, MAHER M	
			ART UNIT 1644	PAPER NUMBER

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,659	MUNDY ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1, 2, 4, 5, 9 and 11, drawn to methods of treating multiple myeloma with alpha4-specific antibodies, classified in Class 424, subclass 130.1.
- II. Claims 1, 3, 6-7 and 11, drawn to methods of treating multiple myeloma with alpha4 Ligand-specific antibodies, classified in Class 424, subclass 130.1.
- III. Claims 1, 2, 4, 5 and 11, drawn to methods of treating multiple myeloma with alpha4beta7-specific antibodies, classified in Class 424, subclass 130.1.
- IV. Claims 1 and 8-11, drawn to methods of treating multiple myeloma with small molecules, wherein the small molecule is BIO-8809, classified in Class 514, subclass 2.
- V. Claims 12-16, drawn to a method of treating multiple myeloma with a first composition comprising alpha4-specific antibodies and a second composition comprising a compound; classified in Class 424, subclass 130.1.
- VI. Claims 12-16, drawn to a method of treating multiple myeloma with a first composition comprising alpha4 Ligand-specific antibodies and a second composition comprising a compound; classified in Class 424, subclass 130.1.
- VII. Claims 12-16, drawn to a method of treating multiple myeloma with a first composition comprising alpha4beta7-specific antibodies and a second composition comprising a compound; classified in Class 424, subclass 130.1.
- VIII. Claims 12-16, drawn to a method of treating multiple myeloma with a first composition comprising small molecules, wherein the small molecule is BIO-8809 and a second composition comprising a compound; classified in Class 424, subclass 130.1.
- IX. Claims 17-18, 20-21, 25 and 27-28, drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with alpha4-specific antibodies, classified in Class 424, subclass 130.1.
- X. Claims 17-18, 20-21 and 27-28, drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with alpha4beta7-specific antibodies, classified in Class 424, subclass 130.1.

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- XI. Claims 17, 19, 22-23 and 27-28, drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with alpha4 Ligand-specific antibodies, classified in Class 424, subclass 130.1.
- XII. Claims 17 and 24-28, drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with small molecules, wherein the small mall molecule is BIO-8809, classified in Class 514, subclass 2.
- XIII. Claims 17-18, 20-21, 25, 27-33, drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with alpha4-specific antibodies and a chemotherapeutic agent, classified in Class 424, subclass 130.1.
- XIV. Claims 17, 19, 22-23 and 27-33, drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with alpha4 Ligand-specific antibodies and a chemotherapeutic agent, classified in Class 424, subclass 130.1.
- XV. Claims 17-18, 20-21 and 27-33, drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with alpha4beta7-specific antibodies and a chemotherapeutic agent, classified in Class 424, subclass 130.1.
- XVI. Claims 17 and 24-33 drawn to methods of inhibiting bone resorption associated with tumors of bone marrow with small molecules a chemotherapeutic agent, wherein the small mall molecule is BIO-8809, classified in Class 514, subclass 2.
- XVII. Claims 34-35, 37, 42, 44-45, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with alpha4-specific antibodies, classified in Class 424, subclass 130.1.
- XVIII. Claims 34, 36, 38-40, 44-45, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with alpha4 Ligand-specific antibodies, classified in Class 424, subclass 130.1.
- XIX. Claims 34-35, 37, and 44-45, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with alpha4beta7-specific antibodies, classified in Class 424, subclass 130.1.
- XX. Claims 34, 41-45, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with small molecules, wherein the small mall molecule is BIO-8809, classified in Class 514, subclass 2.
- XXI. Claims 34-35, 37, 42, 44-50, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with alpha4-specific antibodies and a chemotherapeutic agent, classified in Class 424, subclass 130.1.

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XXII. Claims 34, 36, 38-40 and 44-50, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with alpha4 Ligand-specific antibodies and a chemotherapeutic agent, classified in Class 424, subclass 130.1.

XXIII. Claims 34-35, 37 and 44-50, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with alpha4beta7-specific antibodies and a chemotherapeutic agent, classified in Class 424, subclass 130.1.

XXIV. Claims 34, 41-50, drawn to methods of treating a subject having a disorder characterized by the presence of osteoclastogenesis with small molecules and a chemotherapeutic agent, wherein the small molecule is BIO-8809, classified in Class 514, subclass 2.

2. Groups I-XXIV are different methods. A method of treating multiple myeloma, inhibiting bone resorption, and treating a disorder characterized by osteoclastogenesis differ with respect to ingredients (i.e. various $\alpha 4$ subunit inhibitors), and endpoints; therefore, each method is patentably distinct.

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

4. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If any one of Groups V-VII, XIII-XVI, or XXII-XXIV is elected, applicant is required to elect a single specific chemotherapeutic agent compound such as A) melphalan, B) a biophosphonate, C) Thalidomide, D) erythropoietin, or E) an antagonist of IL6 and an antagonist of IL15. These species are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently.

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5. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
September 29, 2003


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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